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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,313	FREIMER ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A. The claims are directed to nucleotide sequences, polypeptides and methods of using said nucleotide and polypeptide sequence. The nucleotide and polypeptide sequences have differing structure and function. Therefore, the claims are written using improper Markush language. The following SEQ ID NO: and corresponding polypeptide name have been gleaned from the specification:

Protein Name	A. A. SEQ ID NO	N. A. SEQ ID NO
HKNG1	2, 51	1, 5, 7 (exon 10),
HKNG-VI	4, 51	3, 5, 7
HKNG1-V2	36	34 (exon 2')
HKNG1-V3	37	35 (exon 2'')
gphkng1815	39	38
gphkng7b	41	40
gphkng7c	43	42
gphkng7d	45	44
bHKNG1	49	46-48
HKNG1Δ7	66	65, 5, 7

Restriction to one of the following inventions is required under 35 U.S.C. 121:

GROUP I:

1. Claims 1-12, drawn to HKNG1 (SEQ ID NO: 1, 5 and 7), classified in class 536, subclass 23.1.
2. Claims 1-12, drawn to HKNG-VI (SEQ ID NO: 3, 5, 7), classified in class 536 subclass 23.1.
3. Claims 1-12, drawn to HKNG-V2 (SEQ ID NO:34), classified in class 536 subclass 23.1.
4. Claims 1-12, drawn to HKNG-V3 (SEQ ID NO:35), classified in class 536, subclass 23.1.

5. Claims 1-12, drawn to gphkng1815 (SEQ ID NO: 38), classified in class 536, subclass 23.1.

6. Claims 1-12, drawn to gphkng7b (SEQ ID NO: 40), classified in class 536, subclass 23.1.

7. Claims 1-12, drawn to gphkng7c (SEQ ID NO: 42), classified in class 536, subclass 23.1.

8. Claims 1-12, drawn to gphkng7d (SEQ ID NO: 44), classified in class 536, subclass 23.1.

9. Claims 1-12, drawn to bHKNG1(SEQ ID NO: 46-48), classified in class 536, subclass 23.1.

10. Claims 1-12, drawn to HKNG1Δ7 (SEQ ID NO: 65, 5, 7), classified in class 536, subclass 23.1.

GROUP II:

11. Claims 13-15, drawn to HKNG1 (SEQ ID NO: 2, 51), classified in class 530, subclass 350.

12. Claims 13-15, drawn to HKNG-VI (SEQ ID NO: 4, 51), classified in class 530, subclass 350.

13. Claims 13-15, drawn to HKNG-V2 (SEQ ID NO: 36), classified in class 530, subclass 350.

14. Claims 13-15 drawn to HKNG-V3 (SEQ ID NO: 37), classified in class 530, subclass 350.

15. Claims 13-15, drawn to gphkng1815 (SEQ ID NO: 39), classified in class 530, subclass 350.

16. Claims 13-15, drawn to gphkng7b (SEQ ID NO: 41), classified in class 530, subclass 350.

17. Claims 13-15, drawn to gphkng7c (SEQ ID NO: 43), classified in class 530, subclass 350.

18. Claims 13-15, drawn to gphkng7d (SEQ ID NO: 45), classified in class 530, subclass 350.

19. Claims 13-15, drawn to bHKNG1(SEQ ID NO:49), classified in class 530, subclass 350.

20. Claims 13-15, drawn to HKNG1Δ7 (SEQ ID NO: 66), classified in class 530, subclass 350.

GROUP III:

21. Claim 16, drawn to an antibody, classified in class 424, subclass 130.1.

GROUP IV:

22. Claims 17-24, drawn to a method of treating HKNG1 as it relates to the polypeptide sequence (SEQ ID NO:2, 51), classified in class 514, subclass 44.

23. Claims 17-24, drawn to a method of treating HKNG-VI as it relates to the polypeptide sequence (SEQ ID NO:4, 51), classified in class 514, subclass 44.

24. Claims 17-24, drawn to a method of treating HKNG-V2 as it relates to the polypeptide sequence (SEQ ID NO:36), classified in class 514, subclass 44.

25. Claims 17-24, drawn to a method of treating HKNG-V3 (SEQ ID NO:37) as it relates to the polypeptide sequence, classified in class 514, subclass 44.

26. Claims 17-24, drawn to a method of treating gphkng1815 as it relates to the polypeptide sequence (SEQ ID NO: 39), classified in class 514, subclass 44.

27. Claims 17-24, drawn to a method of treating gphkng7b as it relates to the polypeptide sequence (SEQ ID NO: 41), classified in class 514, subclass 44.

28. Claims 17-24, drawn to a method of treating gphkng7c as it relates to the polypeptide sequence (SEQ ID NO: 43), classified in class 514, subclass 44.

29. Claims 17-24, drawn to a method of treating gphkng7d as it relates to the polypeptide sequence (SEQ ID NO: 45), classified in class 514, subclass 44.

30. Claims 17-24, drawn to a method of treating bHKNG1 as it relates to the polypeptide sequence (SEQ ID NO:49), classified in class 514, subclass 44.

31. Claims 17-24, drawn to a method of treating HKNG1Δ7 as it relates to the polypeptide sequence (SEQ ID NO: 66), classified in class 514, subclass 44.

GROUP V:

32. Claims 25-32, drawn to a method of treating HKNG1 as it relates to the nucleotide sequence (SEQ ID NO: 1, 5 and 7), classified in class 514, subclass 44.

33. Claims 25-32, drawn to a method of treating HKNG-VI as it relates to the nucleotide sequence (SEQ ID NO: 3, 5, 7), classified in class 514, subclass 44.

34. Claims 25-32, drawn to a method of treating HKNG-V2 as it relates to the nucleotide sequence (SEQ ID NO: 34), classified in class 514, subclass 44.

35. Claims 25-32, drawn to a method of treating HKNG-V3 as it relates to the nucleotide sequence (SEQ ID NO: 35), classified in class 514, subclass 44.

36. Claims 25-32, drawn to a method of treating gphkng1815 as it relates to the nucleotide sequence (SEQ ID NO: 38), classified in class 514, subclass 44.

37. Claims 25-32, drawn to a method of treating gphkng7b as it relates to the nucleotide sequence (SEQ ID NO: 40), classified in class 514, subclass 44.

38. Claims 25-32, drawn to a method of treating gphkng7c as relates to the nucleotide sequences (SEQ ID NO: 42), classified in class 514, subclass 44.

39. Claims 25-32, drawn to a method of treating gphkng7d as it relates to the nucleotide sequence (SEQ ID NO: 44), classified in class 514, subclass 44.

40. Claims 25-32, drawn to a method of treating bHKNG1 as it relates to the nucleotide sequence (SEQ ID NO: 46-48), classified in class 514, subclass 44.

41. Claims 25-32, drawn to a method of treating HKNG1Δ7 as it relates to the nucleotide sequence (SEQ ID NO: 65, 5, 7), classified in class 514, subclass 44.

GROUP VI:

42. Claims 33-42, drawn to a method of identifying a compound for HKNG1 as it relates to the polypeptide sequence (SEQ ID NO:2, 51), classified in class 435, subclass 4.

43. Claims 33-42, drawn to a method of identifying a compound for HKNG-VI as it relates to the polypeptide sequence (SEQ ID NO:4, 51), classified in class 435, subclass 4.

44. Claims 33-42, drawn to a method of identifying a compound for HKNG-V2 as it relates to the polypeptide sequence (SEQ ID NO:36), classified in class 435 subclass 4.

45. Claims 33-42, drawn to a method of identifying a compound for HKNG-V3 (SEQ ID NO:37) as it relates to the polypeptide sequence, classified in class 435, subclass 4.

46. Claims 33-42, drawn to a method of identifying a compound for gphkng1815 as it relates to the polypeptide sequence (SEQ ID NO: 39), classified in class 435, subclass 4.

47. Claims 33-42, drawn to a method of identifying a compound for gphkng7b as it relates to the polypeptide sequence (SEQ ID NO: 41), classified in class 435, subclass 4.

48. Claims 33-42, drawn to a method of identifying a compound for gphkng7c as it relates to the polypeptide sequence (SEQ ID NO: 43), classified in class 435, subclass 4.

49. Claims 33-42, drawn to a method of identifying a compound gphkng7d as it relates to the polypeptide sequence (SEQ ID NO: 45), classified in class 435, subclass 4.

50. Claims 33-42, drawn to a method of identifying a compound for bHKNG1 as it relates to the polypeptide sequence (SEQ ID NO:49), classified in class 435, subclass 4.

51. Claims 33-42, drawn to a method of identifying a compound for HKNG1Δ7 as it relates to the polypeptide sequence (SEQ ID NO: 66), classified in class 435, subclass 4.

GROUP VII:

52. Claims 33-42, drawn to a method of identifying a compound for HKNG1 as it relates to the nucleotide sequence (SEQ ID NO: 1, 5 and 7), classified in class 435, subclass 4.

53. Claims 33-42, drawn to a method of identifying a compound for HKNG-VI as it relates to the nucleotide sequence (SEQ ID NO: 3, 5, 7), classified in class 435, subclass 4.

54. Claims 33-42, drawn to a method of identifying a compound HKNG-V2 as it relates to the nucleotide sequence (SEQ ID NO: 34), classified in class 435, subclass 4.

55. Claims 33-42, drawn to a method of identifying a compound for HKNG-V3 as it relates to the nucleotide sequence (SEQ ID NO: 35), classified in class 435, subclass 4.

56. Claims 33-42, drawn to a method of identifying a compound for gphkng1815 as it relates to the nucleotide sequence (SEQ ID NO: 38), classified in class 435, subclass 4.

57. Claims 33-42, drawn to a method of identifying a compound gphkng7b as it relates to the nucleotide sequence (SEQ ID NO: 40), classified in class 435, subclass 4.

58. Claims 33-42, drawn to a method of identifying a compound for gphkng7c as relates to the nucleotide sequences (SEQ ID NO: 42), classified in class 435, subclass 4.

59. Claims 33-42, drawn to a method of identifying a compound for gphkng7d as it relates to the nucleotide sequence (SEQ ID NO: 44), classified in class 435, subclass 4.

60. Claims 33-42, drawn to a method of identifying a compound for bHKNG1 as it relates to the nucleotide sequence (SEQ ID NO: 46-48), classified in class 435, subclass 4.

61. Claims 33-42, drawn to a method of identifying a compound for HKNG1□7 as it relates to the nucleotide sequence (SEQ ID NO: 65, 5, 7), classified in class 435, subclass 4.

B. The inventions 1-61 are distinct, each from the other because of the following reasons: Inventions 1-10 (Group I), Inventions 11-20 (Group II) and Invention 21 (Group III) are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct in structure and physicochemical properties. Inventions 1-10 of Group I are drawn to a nucleic acid whereas inventions 11-20 of Group II are drawn to a polypeptide and Invention 21 of Group III is drawn to an antibody. Because the nucleic acid is composed of nucleotides, the polypeptide is composed of amino acids linked by peptide bonds and arrange in complex combinations of alpha helices, beta pleated sheets, hydrophobic and hydrophilic

domains and the antibody is composed of amino acids linked by peptide bonds, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that the nucleic acid is utilized in e.g., hybridization assays as probes for detecting a target of interest, whereas the antibody is utilized in immunological and/or blotting techniques for determining the expression of a target protein or as a therapeutic agent for treatment of an infection. The polypeptide is utilized in e.g., ligand binding assays or to generate antibodies. The nucleic acids of Group I are not required to produce the polypeptides of Group II or the antibody of Group III because antibodies and polypeptides can be isolated directly from nature or chemically synthesized. The antibody of Group III can be produced by other polypeptides. Therefore the different inventions of 1-21 are nonobvious over each other requiring different fields of search. Furthermore, searching the inventions 1-21 as depicted in groups I, II and III together would impose a serious search burden. In the instant case, the search of the polynucleotide, the polypeptide and the antibody are not coextensive. The inventions of Groups I, II and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide and visa versa. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide or antibody but spoke on the gene. The polypeptide and an antibody, which binds to the polypeptide, require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein.

However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide may be known even if a polypeptide is novel. Antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Searching, therefore is not coextensive for the different inventions of Groups I, II and III. The search of each inventions of Groups I, II and III requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the different inventions 1-21 together.

C. Inventions 22-31 (Group IV), Inventions 32-41 (Group V), Invention 42-51 (Group V1) and Invention 52-61 (VII) are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of inventions 22-61 as depicted in Groups IV, V, VI and VII have different modes of operation resulting in different effects. For example, the inventions 22-31 (Group IV) are drawn to a method for treating an individual as it relates to one of the polypeptides sequences SEQ ID NO: 2, 4, 36, 37, 39, 41, 43, 45, 49, 66 or 51 followed by clinical analysis, whereas the inventions 32-41 (Group V) are drawn to a method for treating an individual as it relates to one of the nucleotide sequences SEQ ID NOS: 1, 3, 5, 7, 34, 35, 38, 40, 42, 44, 46-48, 65. The inventions 42-51 (Group VI) are drawn to a method of identifying a compound, as it relates to one of the polypeptides sequences SEQ ID NO: 2, 4, 36, 37, 39, 41, 43, 45, 49, 66 or 51, which are capable of modulating the expression of a desired gene via method of screening in co-immunoprecipitation assays and invention 52-61 (Group VII) is of identifying a compound, as it

relates to one of the nucleotide sequences SEQ ID NOS: 1, 3, 5, 7, 34, 35, 38, 40, 42, 44, 46-48, 65 which are capable of modulating the expression of a desired gene via sequence analysis. The different inventions of Groups IV, V, VI and VII can function independently of each other. A search of the different invention requires a search burden to the Examiner because the searches of the different inventions are not coextensive because the inventions comprise non-overlapping subject matter.

4. Inventions 11-20 (Group II), 21 (Group III) and Inventions 22-41 (Groups IV and V) and Inventions 42-61 (Groups VI and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are nonobvious over each other having different objectives and different modes of operations. For example, the inventions of Group II is drawn to a polypeptide that can function in enzymatic reactions and the invention of Group III is to an antibody that can function is western blotting techniques, whereas the methods of inventions 22-41 as recited in Groups IV and V are drawn to steps for treating an individual with a specific disorder by administering to the individual a drug. The method of inventions 42-61 as recited in the Groups VI and VII are drawn to steps of identifying a compound capable of modulating the expression of a gene of interest using methods well known in the art, e.g. binding assays or via sequence analysis. The inventions of Groups II, III are not required or necessary for the method steps of inventions IV, V, VI or VII. Furthermore the different inventions have different classifications and different fields of search. A search burden exists because the claims comprise non-overlapping subject matter. Thus the searches of the different inventions are not co-extensive.

D. Inventions 1-10 (Group I) and Inventions 32-41 (Group V), Inventions 52-61 Group VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of inventions 1-10 (Group I) can be used in a materially different process, such as in molecular cloning techniques for gene analysis studies. A search burden exists because the claims comprise non-overlapping subject matter. Thus the searches of the different inventions are not co-extensive.

E. Inventions 1-10 (Group I) and Inventions 22-31 (Group IV) and Inventions 42-51 (Group VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct and nonobvious over each other having different functions and effects. For example, the products of invention 1-10 of Group I are drawn to nucleic acid that can function in methods of hybridization and/ or amplification procedures for detecting for e.g. genetic mutations whereas the method of inventions 22-31 of Group IV are drawn to a therapeutic treatment of a disorder by administering a drug to an individual and the method of inventions 42-51 of Group IV are drawn to a method of detecting a compound as it relates to a polypeptide sequence. The products of inventions 1-10 are not required or necessary for the drug treatment or compound classification. Furthermore, the different inventions are distinct base on their divergent classification and different fields of search. A search burden exists because the

claims comprise non-overlapping subject matter. Thus the searches of the different inventions are not co-extensive.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

F. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product

and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

G. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

H. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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